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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/785,260
Filing Date: February 23, 2004
Appellant(s): SHAPIRO ET AL.

Attorney Peter B. Scull
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 19, 2008 appealing from the Office action mailed August 17, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related appeals and interferences.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Action Closing Prosecution

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied on

5972315	Voss et al	10-1999
JP408157346	Matsuda et al	06-1996 **[Complete USPTO Translation Feb 02 2007]**
DE 19849514	Schade	04-2003

(9) The Grounds of Rejection

I. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 11, 12, 14, 15, 19, 20, 21, 22, 24, 25, 26, 28, 30, 31 and 32 stand rejected under 35 U.S.C. 102(b) as anticipated by Voss, U.S. 5,972,315.

B. Claims 11-15,19-26, 28 and 30-32 stand rejected under 35 U.S.C. 102(b) as anticipated by Matsuda et al JP40815734 (June18, 1996).

C. Claims 11, 12, 13, 15, 19, 20, 21, 23, 25, and 31 stand rejected under 35 U.S.C. 102(b) as anticipated by Schade, DE19849514 (May 04, 2000).

Basis for the rejections in view of the claimed language:

Claim 11 has been rejected on all three of the above references which will be considered as the first invention based on the art of record in view of the claimed language which recites:

> "Claim 11: A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga."

The broad claim is drawn to a "composition" consisting essentially of an effective amount up to about 5% by weight of a "root extract of Kaempferia Galanga". The claimed language is definite as to extremely broad scope which is drawn to any composition which may be extracted from the root of Kaempferia Galanga. The only requirement for the claimed composition having an ingredient within 5% that has the functional intended use of protecting skin from "discoloration or harmful effects of tyrosinase". It is noted that the root of "Kaempferia Galanga" as indicated on the record contains at least the following compounds were found to be extracted from the plant material from the "root extract of Kaempferia Galanga":

1. borneol
2. camphene
3. carene
4. 3-Carene borneol
5. 1,8-cineole
6. cinnamic acid ethyl ester
7. ethyl p-methoxycinnamate

8. isoamyl p-methoxycinnamate

9. n-pentadecane

10. p-methoxycinnamic acid ethyl ester

11. p-methoxycinnamic acid methyl ester

12. p-methoxystyrene.

In addition, a computerized West search of the above compounds yielded a total of 9707 hits which are possible anticipatory art when combined with any composition having the compound is within the percentage of up to about 5% in the composition(s). However, the extract per se can be any other compound or compounds that would be possible from an extraction using different extractants since the specification lacks sufficient information pertaining to the scope of the extraction method as well as the scope of the term “root extract” for the components in the extract per se.

Search Results -

Terms	Documents
(borneol or camphene or carene or 3-Carene borneol or 1,8-cineole or cinnamic acid ethyl ester or ethyl p-methoxycinnamate or isoamyl p-methoxycinnamate or n-pentadecane or p-methoxycinnamic acid ethyl ester or p-methoxycinnamic acid methyl ester or p-methoxystyrene)	9707

Furthermore, the broad claimed is drawn to a composition which is drawn to anyone of the above compounds, which includes compound 7, ethyl p-methoxycinnamate. The expression “root extract of Kaempferia Galanga” does not define any compound which expression is the result of a processing step that depends upon the processing conditions to obtain the extract.

It is noted that also the following based on the claimed language whereby the same processing conditions are followed :

“It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see **In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977):”

Since each of the at least eleven compounds can be obtained by the “root extract of Kaempferia Galanga” and any composition comprising up to 5% of the compound can be employed as prior art against the claim and the "PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product" having the functional activity of protecting skin from “discoloration or harmful effects of tyrosinase”.

Furthermore, the claimed compositions with intended use limitations do not impart patentability based on old compositions containing the same components absent a showing that there is a criticality for a particular percentage or any showing of a **patentable difference in** accordance with the following: MPEP 2112:

SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

> "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning,

> does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999)."

Thus the claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable.

Prior Art Rejections

A. Voss teaches in Example 1b, a composition containing a concentration of ethyl p-methoxycinnamate which is 2% that is within the scope of claim 11.

Applicant was required in the Final Rejection to provide evidence that the composition of Voss does not have the required functional activity of protecting skin from "discoloration or harmful effects of tyrosinase" in accordance with "**In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977):"

.

Thus, claims 11, 12, 14, 15, 19, 20, 21, 22, 24, 25, 26, 28, 30, 31 and 32 stand rejected as being anticipatory for the claimed inventions.

B. Matsuda et al anticipates the claims 11-15,19-26, 28 and 30-32 as noted by paragraphs 16, 26, 29, 31, 41-43 and 49 which contains extracts of the claimed plant material within the scope of the claimed percentages

> "[0016]
>
> **Extraction Example 1**
>
> First, the method for **extracting the active extract fractions** from the rhizome of
> **Kaempferia galanga L. is described.**
>
> 1) Starting material

> 1000 g of pulverized powder of the rhizome of Kaempferia galanga L. plant
>
> (2) Extraction
>
> 1 L. of methanol was added to the aforementioned 1000 g of pulverized powder of the
> rhizome of Kaempferia galangal L. plant, and extraction was carried out at 30"C for 3 h by
> stirring at 100 rpm. Also, extraction was further carried out in the same manner using 1 L. of
> methanol.
>
> (3) Pressure filtration
>
> The extract obtained in aforementioned (~) was filtered through a No. 2 filter paper under
> nitrogen gas pressure of 0.1 $kg/cm^{2.}$
>
> (4) Concentration
>
> Vacuum concentration was carried out for the filtrate obtained in the aforementioned (~at 25-30°C and 60-65 torr. As a result, 37.40 g of methanol extract was obtained.

Appellant has not provided any evidence that the claimed active ingredients do not meet the requirements of having the functional activity of protecting skin from "discoloration or harmful effects of tyrosinase" in accordance with " **In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977):"

C. The abstract of Schade clearly teaches as much as needed to anticipate Claims 11, 12, 13, 15, 19, 20, 21, 23, 25, and 31 since the reference teaches isoamyl p-methoxycinnamate which as noted above is one of the compounds that is known to be extracted from the "root of Kaempferia Galanga" which is useful to protecting the skin

from the harmful effects of the sun which composition is within the scope of the claimed inventions absent a showing that the composition per se does not have the functional activity "discoloration or harmful effects of tyrosinase" in accordance with " **In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977):"

II. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 13, 23, 28 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, U.S. 5,972,315.

B. Claims 11-15, 19-26 and 28-32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda et al JP40815734 (June 18, 1996).

The basis for the rejection as noted by claims 12, 13 and 29 which claims illustrate the issue of obviousness which claims are recited:

> Claim 12: A composition according to claim 11 [A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root

extract of Kaempferia Galanga] containing from about 0.1 up to about 5.0 weight percent of the root extract of Kaempferia Galanga.

Claims 13: A composition according to claim 11 [A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga] containing from about 0.2 up to about 1.0 weight percent of the root extract of Kaempferia Galanga.

Claim 29: A composition for protecting mammalian skin according to claim 26 [A composition for protecting mammalian skin from discoloration or the harmful effects of tyrosinase or chemically induced irritation other than UV radiation comprising a preparation containing, in weight percent, an effective amount up to about 5 percent of ethyl p-methoxycinnamate dispersed in a carrier; wherein the ethyl p- methoxycinnamate is extracted from Kaempferia Galanga root] containing from about 0.2% up to about 1.0% of ethyl p-methoxycinnamate (wt/wt).

The issue is that claims 12, 13 and 29 contains a specific range of a root extract for a root extract that may be any root extract that has an intended functional use for "protecting mammalian skin from discoloration or harmful effect of tyrosinase" which range is 0.1% up to about 5.0 % and 0.2 up to about 1.0%. As noted in the above rejections the same facts are drawn to the ingredients which are considered to be the same for the two references. The issue is whether the specific ranges for the same components have an effective amount within the intended functional range only and whether or not the references would render the claims prima facie obvious based on the disclosure of the references.

Prior Art Rejections:

Voss teaches in Example 1b whereby the concentration of ethyl p-methoxycinnamate is 2% as well as disclosure also teaches that the percentage range

is as low as 0.1% which would have been prima facie obvious to one of ordinary skilled in the art to employ absent unexpected or unobvious results.

Matsuda et al teaches several examples which includes extracts which extracts contain at least the ethyl p-methoxycinnamate in the extract as low as 0.1% that renders the claimed ranges prima facie obvious even if the extracts are slightly outside the actual ranges of the final concentration absent a showing of criticality for the claimed ranges.

III. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

Claim 11 and are illustrative examples:

> "Claim 11: A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga."
>
> Claim 21: A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation comprising a preparation containing, in weight percent, an effective amount up to about 5 percent of a root extract of Kaempferia Galanga dispersed in a carrier.

A. Written Description Requirement:

The expression “root extract of Kaempferia Galanga” does not define the "composition" components since the term "extract" is not a known compound but only a process step that depends upon the processing conditions.

The specification lacks adequate written description for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73(Fed. Cir. 1984).

Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, that is the “extract”, is not a description of that material.

Thus, Claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Thus, Claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement since the expression "root extract" does not define the ingredient(s).

B. **The enablement** of the instant specification lack support for the claimed "root extract" since the specification lacks **adequate written description** for the claimed inventions. The description must clearly allow persons of ordinary skill in the

art to recognize what is claimed and essential steps are missing in the claimed inventions since one would reasonably not to expect that any extraction method would yield the intended product obtained from "root extract" of the plant material as well as any material. The specification does not teach or disclose extractions using various extraction techniques that includes physical, thermal, gaseous or various chemical extraction methods. One of ordinary skilled in the art would expect that an aqueous extraction would yield a water soluble liquid extract and insoluble organic products whereas aqueous organism soluble solvent mixtures would yield combinations of water soluble substances and insoluble hydrophobic precipitants.

Thus, Claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific examples or claims not rejected, does not reasonably provide enablement for products defined by only the expression "root extract" without defining the processing conditions or ingredients "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures.

The scope of the expression “root extract of Kaempferia Galanga” encompasses a great number of compounds that exists in the extraction of this plant material. However, the number of extracts far exceeds the one specific compound that is extracted from the plant material which is the only compound listed in the specification. The specification is considered to be totally inadequate in describing the scope of possible compounds extracted from the plant material. In view of the lack of a suitable

written description of the invention containing the claimed subject matter which subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention drawn to the expression "root extract".

In addition, the broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species within the claimed "root extract of Kaempferia Galanga" which have been described by complete structure or identifying characteristics having the specific functional intended use, thus the description requirement has not been satisfied, see **Eli Lilly, 119 F. 3d** 1559, 43 USPQ2d 1398 (Fed. Cir 1997).

(10) Response to argument.

Claim Rejections -35 U.S.C. *§102*

1. ***Rejection of claims 11, 12, 13, 15, 19. 20. 21, 23, 24, 25. 30. and 31 by Voss*** **:**

Appellants' argue on page 10, third paragraph **:**

> "Appellants ' specification and claims disclose and teach a skin-care product, or the root extract components thereof, for protecting against the harmful effects of tyrosinase or chemically induced irritation other than UV radiation, as taught by Applicants' specification and claimed in independent claims 11, 21 and 26. Conversely, Voss describes its skin-care product throughout as "a new cosmetic skin-care product against ageing of the skin as an effect of light", as in col. 1, line 1; col. 1, line 55; and col. 2, line 27. By limiting the Voss cosmetic skin-care

product to this one function, Voss specifically does not include, teach or suggest the element claimed and taught by Applicant, which is protection against the harmful effects of tyrosinase or chemically induced irritation other than UV radiation."

Examiner disagrees since the claims are drawn to the same composition and as indicated in the rejection of the claims in accordance with the following: MPEP 2112:

SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

> "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999)."

In addition, Applicant has failed to provide evidence of any patentable difference in accordance with the decisions noted in the rejections above " **In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977):"

Appellants' argue on page 10, fourth paragraph:

> "Furthermore, the only mention of ethyl p-methoxycinnamate in Voss is in col. 4, line 47. The inclusion of ethyl p-methoxycinnamate, to the extent it is mentioned in this one instance, is as a UV B filter in the amount of 2.0 g in a total emulsion of 100 g. Voss limits inclusion of ethyl p-methoxycinnamate to this one Example I b, and furthermore, limits the role of ethyl p- methoxycinnamate to the role of a UV B filter at a 2.0% concentration. By such limitation, Voss does not include, teach or suggest the "other than UV limitation" of Applicants' claims and rather, teaches away from use of ethyl p-methoxycinnamate as anything but a UV B filter in a 2.0% concentration."

Examiner disagrees since the example is anticipatory art containing the same compound for whatever it is used for the composition contains the claimed compound within the old composition.

Appellants' argue on page 11, first paragraph:

> "Moreover, Appellants 'composition of Kaempferia Galanga root extract is not taught or suggested by Voss whether for this or any other purpose, let alone that of Appellants' root extract serving an entirely different function than the Voss composition. Appellants' claimed composition is of a Kaempferia Galanga root extract as protective against the harmful effects of tyrosinase or chemically induced irritation but specifically does not include Kaempferia Galanga root extract as a protectant against UV radiation."

Examiner disagrees since the claims are drawn to an extract per se that does not require the anything other than the effective compound(s) from the extraction of the root of Kaempferia Galanga. It is immaterial how one obtains the compound(s) which claims do not require any other components of the extract per se.

Appellants' argue on page 11, second paragraph:

> "The Examiner appears to state that the products are identical or substantially identical, and to require that the Appellants to prove that the prior art products do not inherently possess the characteristics of the claimed product. In re Brown, 459 F.2d 531 (CCPA 1972). As a preliminary matter, the products are different. The claimed product here is specifically intended for "protecting mammalian skin from discoloration or the harmful effects of tyrosinase or chemically induced irritation other than UV radiation". This is not an inherent characteristic of the Voss product, which "is based on UV-radiation-absorbing substances [necessarily] in combination with a free-radical scavenger system". Note, persons using the Voss product for treatment of sunburn would not inherently be treating a tyrosinase or chemical irritant or discoloration issue as provided here. There is thus no inherency from Voss."

Examiner disagrees since Appellants have failed to provide the required showing that there is a patentable difference in view of the decisions pertaining to " **In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977):" Applicant has stated that the "products are

different" but the claimed subject matter does not indicate any claimed product that is different from the reference which claim 11 recites:

> "Claim 11 : A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga."

The composition is drawn to one single compound disclosed which is ethyl p-methoxycinnamate "an effective amount of up to about 5%".

Furthermore, the intended use of an old composition as argued "other than UV radiation" carries little weight absent a showing that Appellants were requested to submit but have refused to be in compliance with to support the argued difference(s) over the art of record.

2. Rejection of claims 11, 12, 14, 15, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 31 and 32 by Matsuda et al:

Appellants argue the following on page 12, second paragraph:

> "The Matsuda patent is entitled "UV Absorptive Skin Cosmetic", and is described as "a UV absorptive skin cosmetic characterized by having high safety and comprising a plant extract having UV absorptive effect". The objective of the invention in Matsuda is to protect the skin against harmful UV light, unlike the limitations of Appellants' patent claims. Matsuda is a UV protectant. Appellants ' invention is a non-UV protectant. These are not identical and thus Matsuda does not anticipate. Note here also, persons using the Matsuda product for treatment of sunburn would not inherently be treating a tyrosinase or chemical irritant or discoloration issue as provided here. There is thus no inherency from Matsuda. In order to sustain a rejection under 35 USC 102(b), the references cited, i.e. Matsuda, here, must teach or disclose each and every element of the claimed invention. Matsuda does not teach each and every element of Appellants'

> amended claims 11,21 and 26. Thus, Appellants' claims 11, 21 and 26 are believed to be allowable over Matsuda."

Examiner disagrees since the reference product is within the scope of the claimed language and there is no showing of any patentable difference and the intended use of the old composition is not patentable for the same reasons as noted above.

3. Rejection of claims 11-13, 15, 19-21, 23, 25 and 31 by Schade:

Appellants' argue the following on page 12, first full paragraph:

> "The Schade patent, to the best of Appellants' understanding, references neither extract of Kaempferia Galanga nor a non-UV protectant. The reference cited by the examiner is isoamyl p- methoxycinnamate, also known as amiloxate. The mere fact that the Schade reference teaches a UV protectant for a potential substituent of a Kaempferia Galanga root extract does not teach or suggest the root extract itself nor that it would act as an "other than UV" protectant. Therefore, the Schade patent does not constitute disqualifying prior art. "

The issue is that isoamyl p-methoxycinnamate as evidenced on the record as being one of at least eleven compounds that have been extracted from the root of Kaempferia Galanga. The reference teaches that the composition is employed as a sun protectant which composition containing the specific compound renders the composition unpatentable in view of **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977):" Applicant has stated the reference composition does not teach or suggest "that it would act as an "other than UV" protectant.", which Appellants have failed to demonstrate a patentable difference.

Claim Rejections -35 U.S.C. *§103*

1. Rejection of claims 13, 23, 28 and 29 on Voss

Appellants' argue on page 14

> "Examiner has rejected these claims, "...in view of Example I b of Voss, wherein the concentration of the ethyl p-methoxycinnamate is 2% further in view of the disclosure which teaches that the percentage range is as low as 0.1%..." Appellants respectfully traverse this rejection.
> Appellants incorporate their above arguments with regard to Voss, supra, and submit that Appellants' claims 13, 23, 28 and 29 are believed to be allowable at least, because: i) they contain limitations not taught or suggested by Voss; and ii) they depend from allowable independent claims 11,21 and 26, respectively."

> "More specifically, Voss doesn't teach or suggest the limitations of the base claims 11, 21 or 26 including the "root extract" and "other than UV radiation" limitations, regardless the weight percents given. There is further no supplementation nor source or citation of a basis by the Examiner whether in or from Voss or some other prior art reference. Thus, the dependent claims 13, 23, 28 and 29 are not obvious from Voss and should be allowed.

Examiner disagrees with the above in view of the following:

The argued limitations which includes the percentages have been addressed in the rejections and that the primary and essentially only argued limitation is drawn to a new use for an old composition. The issues with "root extract" and "other than UV radiation limitations" have been considered not to patentable based on the record especially since Appellants' have failed to provide evidence of any patentable difference over Voss.

Appellants have argued the following on page 14:

> "Note, as a final matter, an Examiner taking "Official Notice" of the basic knowledge or common sense of a person of ordinary skill in the art to supplement the specific teachings of the art, must provide some form of evidence in the record to support such an assertion of common knowledge. In re Zurko, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection . Moreover, if the Examiner relies on his or her personal knowledge to supplement what is actually known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the supplementation. 37 CFR 1.104(d)(2).
>
> Here, the Examiner provides no such evidence or affidavit supporting the Examiner's apparent taking of Official Notice and the assertion that Appellants' development would have been obvious to one skilled in the art. The Examiner has failed to provide any affidavit or other evidentiary support for the assertion that it would be obvious to extend the teachings of Voss for use in connection with a composition such as that disclosed in Appellants' application. In response hereto, Appellants respectfully request such evidence or affidavit according to rule 37 CFR 1.104(d)(2)."

Examiner disagrees with the comments submitted by Appellants' stating

"….Here, the Examiner provides no such evidence or affidavit supporting the Examiner's apparent taking of Official Notice".

Appellants' have not specifically indicated the argued "Official Notice" or alleged assertion in the rejections. The only indication for obviousness is drawn to the "the percentage range is as low as 0.1%..." in Voss which rejection is based on the teachings in the reference that recites the following:

> 1. **A cosmetic** vitamin E skin penetrate composition, comprising by weight:
> 0.3 to 10% of a vitamin E derivative selected from the group consisting of vitamin E linoleate, vitamin E acetate and mixtures thereto;
> 0. 1 to 10% of 2-(dihydroxyethyl)-2-hydroxy-6,10,14-trimethyl-pentadecane; and
> **at least one UV filter.**
> 4. The composition of claim 1, wherein said **one or more UV filter is present in an amount of 0.1 to 20%.**

5. The composition of claim 1, wherein said vitamin E derivative is present in an amount of 0.3-8%; said 2-(dihydroxyethyl)-2-hydroxy-6,10,14-trimethyl-pentadecane is present in an amount of 0.3 to 5% and **said UV filter is present in an amount of 0.3 to 10%.**

The rejection has not been based completely on the disclosure of the reference that any one who is able to read that 0.1% to 20% would be within the scope of the claimed limitation range of 0.1 to about up to about 5.0 % which is just plain common sense for any ordinary person skilled in the art.

2. Rejection of claims 11-15, 19-26 and 28-32 on Matsuda et al.

Appellants' have argued on Page 15 the following :

"More specifically, Matsuda doesn't teach or suggest the limitations of the base claims 11, 21 or 26 including the "root extract" (apparently not an extract by the same or similar process of Appellants' description) or the "other than UV radiation" limitations. There is further no supplementation nor source or citation of a basis by the Examiner whether in or from Matsuda or some other prior art reference. Thus, both the independent and the dependent claims are not obvious from Matsuda and should be allowed."

Examiner disagrees with the above arguments based on the disclosure of Matsuda et al as indicated in paragraphs 21-23, 26, 29, 31, 36, 37, 41-43 and 49 which teaches compositions containing extracts within certain parameters that renders the instant claims prima facie to one of ordinary skilled in the art having this prior art which art includes at least the ethyl p-methoxycinnamate in the extract within the composition..

Appellants' have argued on page **15**

"Note, as a final matter, an Examiner taking "Official Notice" of the basic knowledge or common sense of a person of ordinary skill in the art to supplement the specific teachings of the art, must provide some form of evidence in the record to support such an assertion of common knowledge. In re Zurko, 258 F.3d 1379, 1386, 59 U.S.P.Q.2dl693, 1697 (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill

> in the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection). Moreover, if the Examiner relies on his or her personal knowledge to supplement what is actually known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the supplementation. 37 CFR 1.104(d)(2).
>
> Here, the Examiner provides no such evidence or affidavit supporting the Examiner's apparent taking of Official Notice and the assertion that Appellants' development would have been obvious to one skilled in the art. The Examiner has failed to provide any affidavit or other"

Examiner disagrees with the statement made by Appellants without any indication or showing on the record pertaining to the allegation that "Examiner's apparent taking of Official Notice". Examiner makes the statement that all evidence on the record are based on concrete evidence in the examples or teachings in the prior art of record which support the findings and rejections that Appellants lack any patentable subject matter based on the instant claims.

Claim Rejections*-35 U.S.C. *§ll2-Claims ll, 12, 13, 15, 19-21, 23-25, 30 and 31

Appellants' have argued on page 6, second full paragraph that :

> "The result of the extraction process is a definite product, which thus is clearly enabled by the very specific process set forth in the specification." and
>
> "The result of the extraction process is a definite product, which thus is clearly enabled by the very specific process set forth in the specification."

Examiner disagrees with the above as indicated in the rejection since the rejected claims are not commensurate in scope with the enabling disclosure that are lacking the "very specific process" conditions in view of the fact that the specification does not support the broad scope which specific process steps are not in the instant claims. As

indicated above, Appellants are enabled for specific examples , because the specification, while being enabling for the specific examples, does not reasonably provide enablement for products defined by only the expression "root extract" without defining the processing conditions or ingredients "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures.

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

Appellants have argued on Page 6 , third full paragraph :

"...the Examiner urges that "[t]he expression **"root extract"** does not define the ingredient(s)." Appellants' stated "For enablement, this is not relevant, necessary, nor required. Practitioners need merely be taught how to "make and use" the invention. They have here, and thus the rejection is overcome, obviated or traversed".

Examiner disagrees with the above since the following requirements based on 35 USC 112 first paragraph which recites:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The **specific rejection** under this heading is drawn to **"scope of enablement"** based on some parts of the specification is enabled to make and use for some claims that are commensurate in scope the enabling disclosure. The form paragraph for the scope of enablement is as follows:

> Claim*** rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ***, does not reasonably provide enablement for ***. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to *** the invention commensurate in scope with these claims. ***.

Examiner has indicated claims that are enabled but have rejected those claims which do not meet the conditions to make and use as noted in the rejection due to the factual situation the specification lacks suitable "written description" commensurate in scope with the enabling disclosure to make and practice the invention(s) commensurate in scope with these claims.

Appellants' have argued on Page 6 last paragraph 6th line up from bottom of page:

"..the Examiner reiterates his allegation that the Applicant has failed to provide the information for the claimed 'extract'. ..Again this is not relevant, necessary, nor required. Examiner asks for a decision by the Board of Appeals or other officials based on this specific issue. …Simply put, the Examiner is refusing this application due to the invention's nature as an "extract". The "decision" requested by the Examiner is present

in an abundance of existing, still valid case law regarding the specific issue of extracts and extraction."

Examiner disagrees with the position of Appellants that:

"Examiner is refusing this application due to the invention's nature as an "extract".

This Examiner has allowed the parent application , Patent Number 6,719,964 , which includes claim 9 that has been allowed pertaining to an allowable extract.

> 1. A method of protecting mammalian skin from the harmful effects of tyrosinase and chemically induced irritation other than UV radiation comprising applying to skin in need thereof a preparation containing, in weight percent, an effective amount up to about 5 percent of ethyl p-methoxycinnamate dispersed in a nontoxic, nonirritating cosmetically acceptable carrier.
>
> 9. A method according to claim 1 in which said ethyl p-methoxycinnamate is extracted from Kaempferia Galanga root.

Appellant's have argued on page 9, the following:.....

> "Converse to the examiner's assertion that the term "root extract" does not define the ingredients, or "does not define structures, physical or chemical properties of compounds," Office Action, page 6, lines 22-23, the extraction process defines the expression "root extract". The term is clear and it defines the "metes and bounds" of the claimed in'0ention. Note, Appellants have previously stated that use of the term "extract" is common in patent lexicography relating to derivatives of organic matter, as evidenced by the patents and prior art listed in the brief summary of the invention section of the initial patent filing. See also Exhibit A., US Patent Office database of patents issued since 1976 with claims including the phrase "root extract"; resulting in at least 77 patents since 1976 (http//:patft.uspto.gov/...);which.doesn't even begin to reach all "extract" claims for seed extracts, plant extracts, or extracts from other living or non-living matter. Use of the term "extract" does not render the claims of a patent indefinite nor vague, as often the term "extract" may be the most accurate and complete means of describing a constituent and essential ingredient of the claimed invention. This may be true here, where it may be incomplete to refer to the identity of the effective ingredients without making reference to the means of derivation from a root or other organic material. "

Examiner disagrees with the position of Appellants.

This has been the first time this Examiner has had the opportunity to request a Board decision based on the expression or term involving "extract" of plant(s) or living microorganisms. An appropriate decision by this Board would expedite the prosecution in future applications.

Appellants' have indicated in Exhibit A at least 77 patents containing the expression “root extract” of which 77 patents this Examiner had allowed 9 of the 77 applications cited. The issues in at least two of the nine patents are essentially based on the same issue as in this application as noted by the following:

See Reference No 23: US Patent 6,676,974 [Patent Application 10/105794]

Whereby Applicant had elected product claims 11-12 for examination which recite the following:

> 11. A pharmaceutical composition useful for treating fuloroquinolone resistant bacterial infections including enteric and systemic infections, said composition comprising 10 to 50% by wt of root extract of vetiver, 0.4 to 1% by wt of citric acid, 10 to 20% by wt of calcium carbonate, 10 to 20% by wt of magnesium hydroxide gel, 20 to 60% by weight of lactose and optionally comprising other pharmaceutically acceptable additives.
>
> 12. The pharmaceutical composition as claimed in claim 11 is optionally compounded with honey by dispersing the constituents in honey.

The rejection as submitted was:

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention…

Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific extracts per se, does not reasonably provide enablement for any “root extract of vetiver”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims, see the following

Claim are rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. An Aextract≅ is necessarily a product-by-process because the composition of the Aextract≅ is only defined by the process of its preparation. Such product-by-process claims are intended to define products, which are otherwise difficult to define and/or distinguish from the prior art except, by the process of making. Since any given biological source contains thousands of extractable compounds, each with it=s own particular extraction properties, the nature of the resulting Aextract≅ will depend on the conditions of the extraction and the solvent used. For example, at what temperature is the extraction performed? Is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, or an acid or base, or is it a squeezed extract? It is well accepted in the natural products and herbal art, that extraction of a biological source with one of various distinct solvents has a profound impact on the final product with respect to the presence, amounts, and/or ratios of active ingredients obtained, and, thus, on the ability of the Aextract≅ to provide the desired functional effect(s) claimed and/or disclosed. Since the Aextract≅ itself is clearly essential to the instantly claimed invention, the step(s) by which the claimed Aextract≅ is/are obtained is/are also clearly essential and, therefore, must be recited in the claims (i.e., as a product-by-process). Although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, **with all its claimed limitations**, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material generally known to exist, **in the absence of knowledge as to what that material consists of, that is the Aextract≅ , is not a description of that material.**

Thus, Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The broad claims lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the claims lack sufficient process steps in according with the specification since the specification does not indicate the complete structure of the components of the extracts or identifying characteristics.

The Patent was issued as follows in the next office action by amendment:

1. A process for the isolation of bioactive fraction of the plant Vetivera zizanioides comprising the steps of: a) powdering the plant part of Vetivera zizanioides, b) extracting the plant powder of step (a) by soaking in protic aqueous organic solvent for a period of 16-20 hours, c) filtering the organic solvent extract of step (b), d) evaporating the extract of step (c) under reduced pressure to remove the organic solvent to obtain an aqueous extract, e) lyophilising the aqueous extract of step (d) to get an powdered extract, f) dissolving the powdered extract of

step (e) in 2% aqueous citric acid, g) extracting the solution of step (f) successively with chloroform, n-butanol, methanol and finally with acetone to obtain respective organic extracts and an aqueous solution, h) evaporating separately the organic extracts of step (g) to obtain respective residues, i) neutralizing the aqueous solution of step (g) with ammonia solution, j) testing the bioactivity of residues obtained in step (h) and neutralized solution of step (i) to identify residue from methanolic extract as bioactive residue, k) macerating the residue of methanoloic extract of step (h) successively with hexane, chloroform and ethylacetate, l) testing bioactivity of hexane, chloroform ethylacetate fractions of step (k) to identify hexane fractions as a bioactive fraction, m) purifying the residue of hexane faction of step (l) on a silica gel column using eluant hexane and mixture of hexane-chloroform with increasing polarity, and n) evaporating the hexane-choroform (1:1) eluant fraction obtained from step (m) to yield a residue, which is purified by thin layer chromatography to achieve the required bioactive fraction.

15. A pharmaceutical composition useful for treating fluoroquinolone resistant bacterial infections including enteric and systemic infections, said composition comprising 10 to 50% by wt of the root extract of vetiver **obtained by the process of claim 1**, 0.4 to 1% by wt of citric acid, 10 to 20% by wt of calcium carbonate, 10 to 20% by wt of magnesium hydroxide gel, 20 to 60% by wt of lactose and optionally comprising other pharmaceutically acceptable additives.

16. The pharmaceutical composition as claimed in claim 15 is optionally compounded with honey by dispersing the constituents in honey.

Another one of the submitted Patents listed as No 24 US 6,652,891 which Composition originally claimed:

1. A composition useful as a dietary supplement which composition comprises an emulsion comprising an oil phase and a water phase wherein said oil phase comprises: (a) vegetable oil; (b) coenzyme Q10; (c) an emulsifier; and wherein the water phase comprises water.

A composition according to claim 1 wherein the water phase also comprises at least one additive selected from the group consisting of extract of the

fruit of Lou Han, extract of the leaves of Stevia, L-carnitine fumarate, Chinese licorice root extract, thickeners, gelling agents, flavor stabilizing agents, glycerine, and combinations of the foregoing

The issue that the above "extract(s)" were found not to be enabling which claims were allowed in US 6,652,891 with the following

EXAMINER'S AMENDMENT

An examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

In **Claim 1, line 8,** after "comprises water " **add** the following:

---- and at least one additive selected from the group consisting of aqueous or alcoholic extract of the fruit of Lou Han, aqueous or alcoholic extract of the leaves of Stevia, aqueous or alcoholic Chinese licorice root extract and combinations of the foregoing ---------.

The final allowed claim was:

1. A composition useful as a dietary supplement which composition comprises an emulsion comprising an oil phase and a water phase wherein said oil phase comprises: (a) vegetable oil; (b) coenzyme Q10; (c) an emulsifier; and wherein the water phase comprises water and at least one additive selected from the group consisting of aqueous or alcoholic extract of the fruit of Lou Han, aqueous or alcoholic extract of the leaves of Stevia, aqueous or alcoholic Chinese licorice root extract and combinations of the foregoing.

Examiner kindly requests an appropriate decision based on the current issue whereby the instant application contain claims:

a) which have been defined by purely functional term

and

b) the issue of scope of enablement whereby claims have been found to be enabled for specific examples,

which issues are similar to the "functional limitations" and "metes and bounds" issues decided in a recent decision in Halliburton Services, Inc. v. M-I LLC, No. 6:05-CV-155 (E.D. Tex. Nov. 20, 2006) which was drawn to second paragraph:

> **"112(2) and functional limitations** - When a claim limitation is defined in purely functional terms, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context.
>
> > It is highly desirable that patent examiners demand that applicants resolve the ambiguity in the patent claims so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation.
>
> **When a claim limitation is defined in purely functional terms**, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area). We note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation."

The above issue in the instant application is that there are claims that are defined by purely functional terms which includes "root extract".

> **"Claim Construction & Scope - where a claim is ambiguous as to its scope, adopt a narrowing construction when doing so would still serve the notice function of the claims**
>
> We note that where a claim is ambiguous as to its scope we have adopted a narrowing construction when doing so would still serve the notice function of the claims. See Athletic Alternatives, 73 F.3d at 1581 ("Where

> there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning."). In this case, however, Halliburton asks that we resolve the ambiguity in a way that gives it the broadest possible construction (i.e., that its claim covers all future improvements without regard to whether Halliburton invented such improvements); such a construction would undermine the notice function of the claims because it would allow Halliburton to benefit from the ambiguity, rather than requiring Halliburton to give proper notice of the scope of the claims to competitors."

(11) Conclusion

For the above reasons, it is believed that the rejections and/or findings of patentability discussed above should be sustained.

Respectfully submitted,

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